

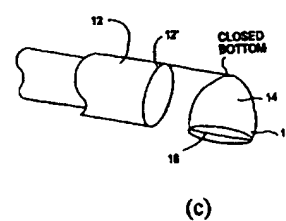
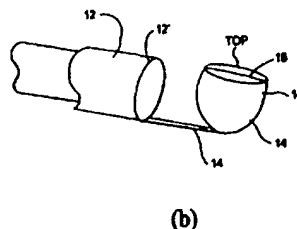
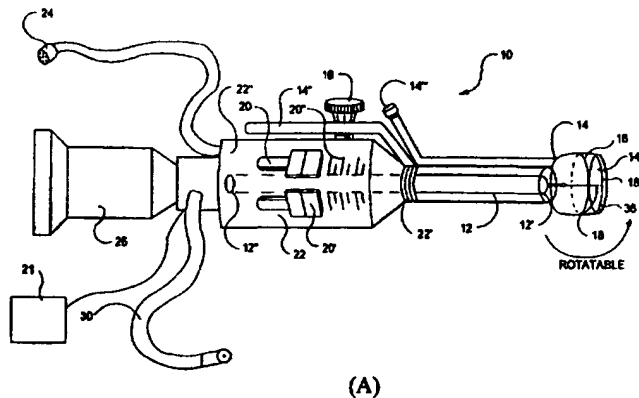


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: A61B 17/39	A1	(11) International Publication Number: WO 97/41787 (43) International Publication Date: 13 November 1997 (13.11.97)
(21) International Application Number: PCT/US97/03550 (22) International Filing Date: 6 March 1997 (06.03.97) (30) Priority Data: 08/643,524 6 May 1996 (06.05.96) US (71) Applicant (for all designated States except US): SOMNUS MEDICAL TECHNOLOGIES, INC. [US/US]; 995 Benicia Avenue, Sunnyvale, CA 94086 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): EDWARDS, Stuart, D. [US/US]; 658 Westridge Drive, Portola Valley, CA 94028 (US). (74) Agent: DAVIS, Paul; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: ABLATION APPARATUS AND SYSTEM FOR REMOVAL OF SOFT PALATE TISSUE**(57) Abstract**

An ablation apparatus suitable for the ablation of soft palate tissue, including but not limited to the uvula, includes a cannula with a distal end and a proximal end and a lumen. A vacuum assisted retainer device is coupled to the cannula distal end. The vacuum retainer member includes a uvula receiving member configured to retain at least a portion of the uvula with the application of vacuum. An electromagnetic electrode is coupled to an electromagnetic energy source. A vacuum source is coupled to the uvula receiving member.



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Cross Reference to Related Applications

10 BACKGROUND OF THE INVENTION

This invention relates generally to an ablation apparatus for the removal of a variety of tissues, and more particularly to an RF, microwave, or laser fiber apparatus which ablates soft palate tissue including a portion of the uvula to treat snoring disorders.

Generally, there are two types of snoring. They are distinguished, depending on the localization of their origin. The first type of snoring, velar, is produced by the vibration of all of the structures of the soft palate including the velum, the interior and posterior arches of the tonsils and the uvula. Velar snoring results from a vibration of the soft palate created by the inspiratory flow of air, both nasal and oral, which makes the soft palate wave like a flag. The sound intensity of these vibrations is accentuated by the opening of the buccal cavity which acts as a sound box.

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These two types of snoring may easily be combined in the same individual.

For some years there have been surgical techniques for correcting apnea. However, maxillary surgery to cure pharyngeal snoring requires major surgery, with the operation lasting several hours, and the uvula-palatopharyngoplasty procedure to correct velar snoring is not without draw backs. This explains the popularity of prosthesis and other preventive devices.

More recently, portions of the soft palate have been removed by laser ablation. If too much tissue is removed, severe consequences result. The degree of laser ablation is difficult to control and multiple treatments are usually required. Further, patients have a high degree of soreness in their throats for many weeks.

U.S. Patent No. 4,423,812 discloses a loop electrode design characterized by a bare active wire portion suspended between wire supports on an electrode shaft. Tissue stripping is effected with a bare wire, and the adjacent portions of the wire supports an electrode shaft that is made insulating to prevent accidental burns to the patient, allowing the physician to use these insulated parts to help position and guide the active wire portion during the surgical procedure. However, this requires that the physician shave off, during multiple visits, successive thin superficial layers of the obstructing tissues to avoid gross resection and its adverse affects.

U.S. Patent No. 5,046,512 discloses a method for the treatment of snoring and apnea. The method regulates air flow to the user to an extent comparable to the volume of air which flows through the users nasal passages. An associated apparatus provides a device having a body portion sufficiently wide to separate the users teeth. It includes an air passage comparable in area to the area of the user's nasal passages.

The use of oral cavity appliances has been proposed frequently for the treatment of sleep disorders. It has been recognized that movement of the mandible forward relative to the maxilla can eliminate or reduce sleep apnea and

snoring symptoms by causing the pharyngeal air passage to remain open.

Several intra-oral dental appliances have been developed which the user wears at night to fix the mandible in an anterior protruded position. Such dental appliances essentially consist of acrylic or elastomeric bit blocks, similar to
5 orthodontic retainers or athletic mouth guards, which are custom fitted to a user's upper and lower teeth. The device may be adjusted to vary the degree of anterior protrusion.

U.S. Patent 4,901,737 discloses an intra-oral appliance while reducing snoring which repositions the mandible in an inferior, open, and anterior,
10 protrusive, position as compared to the normally closed position of the jaw. Once the dentist or physician determines the operative snoring reduction position for a particular patient, an appropriate mold is taken for the maxillary dentition and of the mandibular dentition to form an appliance template. This device includes a pair of V-shaped spacer members formed from dental acrylic which
15 extend between the maxillary and mandibular dentition to form a unitary mouthpiece.

While such dental appliances have proven effective in maintaining the mandible in a protruded position to improve airway patency, they often result in undesirable side effects. One of the most common side effects is aggravation of
20 the tempromandibular joint and related jaw muscles and ligaments, especially in individuals who have a tendency to grind their teeth during sleep. Aggravation of the tempromandibular joint has been associated with a wide variety of physical ailments, including migraine headaches. Accordingly, many individuals suffering from sleep apnea and snoring disorders are not able to tolerate existing anti-
25 snoring dental appliances for long periods of time.

It would be desirable to provide an ablation apparatus which eliminates the need for dental appliances for the treatment of snoring and sleep apnea disorders. It would also be desirable to provide a treatment device which is not
30 an intra-oral dental appliance, and which can effectively and safely remove selected portions of the soft palate without providing the patient with undesirable

side effects. Further, it would be desirable to provide a tissue ablation device which retains the targeted ablation tissue during the ablation process.

SUMMARY OF THE INVENTION

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Accordingly, it is an object of the invention to provide an ablation device which is useful with a variety of tissues, and includes a retaining member to retain the tissue as it is ablated.

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Another object of the present invention is to provide an ablation apparatus to treat snoring disorders.

A further object of the invention is to provide an ablation apparatus which can use a variety of electromagnetic energy sources to remove soft palate tissue and treat snoring disorders.

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Yet a further object of the invention is to provide an ablation apparatus which can use a variety of electromagnetic energy sources, includes a retaining member to retain the tissue as it is ablated, and is suitable for ablating soft, hard, cartilage and mucosal tissues.

Yet another object of the invention is to provide an ablation apparatus to ablate sections of the uvula and other soft palate tissue.

20

Still another object of the invention is to provide an ablation apparatus including an anvil to position the uvula for ablation.

Another object of the invention is to provide an ablation apparatus including a vacuum retainer to position and retain the uvula and other soft palate tissue during ablation.

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A further object of the invention is to provide an ablation apparatus which uses an RF energy source to ablate selected sections of the uvula and other soft palate tissue.

Yet another object of the invention is to provide an ablation system that includes a retaining member to retain an ablated tissue site, and the retaining

member can be retracted so that an electromagnetic energy delivery source can be utilized without the retaining member.

5 These and other objects of the present invention are achieved in an ablation apparatus that includes a cannula with a distal end and a proximal end and a lumen. A vacuum assisted retainer device is coupled to the cannula distal end. The vacuum retainer member includes a uvula receiving member configured to retain at least a portion of the uvula with the application of vacuum. An electromagnetic electrode is coupled to an electromagnetic energy source. A vacuum source is coupled to the uvula receiving member.

10 In one embodiment of the invention, a method of ablating a portion of a uvula includes an ablation apparatus. The ablation apparatus includes a vacuum assisted retainer device coupled to the cannula distal end. The vacuum assisted retainer member consists of a uvula receiving member configured to retain at least a portion of the uvula with the application of a vacuum, and an
15 electromagnetic energy electrode. At least a portion of a uvula is introduced in the uvula receiving member. A vacuum is applied to the uvula and retains the uvula in the uvula receiving member. Electromagnetic energy is applied from the electrode to the uvula in the uvula receiving member. An ablation lesion is formed within the uvula.

20 A variety of different tissues can be ablated, included but not limited to soft, hard, and mucosal tissue, as well as cartilage. The present invention is particularly suitable in ablating soft palate tissue for purposes of ablation and effecting a cure for snoring. The uvula can be retained by the retaining member as one or more electromagnetic energy delivery devices are advanced and
25 retracted out of the uvula. Once the desired level of uvula ablation is achieved, the retaining member can be rotated and retracted in order to provide a straight shot for the electromagnetic energy delivery devices to be introduced into tissue that does not require retainment during ablation.

30 A variety of different electromagnetic energy sources can be used such as RF, microwave, laser, and the like. The electromagnetic energy delivery

device can be an RF electrode (operated in mono-polar and bi-polar modes), a microwave antenna, an optical delivery fiber and the like.

5 When an RF electrode is used, an insulator can be positioned to surround the RF electrode and may be capable of slideable movement along an exterior of the electrode. This permits the length of an RF ablation surface to be varied. Further, the distal end of the anvil can be a ground pad electrode.

One or more sensors can be incorporated at the cannula distal end and in the retaining member and its distal end. The cannula can have a hollow central lumen with one or more fluid distribution ports. A visualization apparatus can be
10 positioned in the lumen. An eyepiece is coupled to the visualization apparatus at a proximal end of the cannula.

A flushing port can be formed in a cannula lumen. The flushing port is positioned near a distal end of the visualization apparatus in order to introduce a flushing medium past visualization apparatus distal end.

15

BRIEF DESCRIPTION OF THE FIGURES

Figure 1(a) is a perspective view of the tissue ablation apparatus of the present invention, including a rotatable retaining member coupled to a vacuum source.

20 Figure 1(b) is a perspective view of the top of the retaining member of Figure 1(a).

Figure 1(c) is a perspective view of a closed bottom of the retaining member of Figure 1(a).

25 Figure 2 is a perspective view of the cannula with a needle electrode or antenna and the retaining member of Figure 1(a).

Figure 3 is a perspective view of the distal end of the cannula and an electromagnetic energy delivery device extending beyond the cannula's distal end, establishing an optical length.

30 Figure 4 is a perspective view of a distal end of the cannula, with a thermal sensor and the retaining member of Figure 1(a).

Figure 5 is a perspective view of the apparatus of the present invention with a handle.

Figure 6 is an exploded view of the retaining member of Figure 1(a) and the cannula.

5 Figure 7 is a perspective view of a flushing port or optic port associated with the retaining member of Figure 1(a).

Figure 8 is a block diagram illustrating the inclusion of a controller, power source and other electronic components of the present invention.

10 Figure 9 is a block diagram illustrating an analog amplifier, analog multiplexer and microprocessor used with the present invention.

DETAILED DESCRIPTION

Referring now to Figure 1(a) a soft tissue ablation apparatus 10 includes a cannula 12, a cannula distal end 12', a cannula proximal end 12" and a cannula lumen 12". A retaining member 14 is coupled to cannula 12 and extends beyond
15 distal end 12'. Retaining member 14 has a distal end 14' with a geometry that is adapted to surround an exterior of the uvula. A top of retaining member is open in order to receive the uvula. A bottom of the retaining member may be closed. Distal end 14' is adapted to capture, receive and retain a tissue ablation target
20 during the ablation process.

A variety of different tissues can be ablated, included but not limited to soft, hard, and mucosal tissue, as well as cartilage. The present invention is particularly suitable in ablating soft palate tissue for purposes of ablation and effecting a cure for snoring. The uvula can be retained by retaining member 14
25 as one or more electromagnetic energy delivery devices deliver electromagnetic energy to the uvula. Once the desired level of uvula ablation is achieved, retaining member 14 is removed.

Retaining member 14 can be fastened with a fastener 16, including but not limited to a ground adjustment nut, and to the body of cannula 12.
30 Alternatively, retaining member 14 can be integrally formed with cannula 12. A

retaining member proximal end 14" can include a flushing port 14'" that is adapted to receive a flushing medium. Retaining member 14 can be rotatable relative to cannula 12.

5 Retaining member 14 can have a variety of different geometries such as an a cup-shaped member (Figure 1(a)), with an open top (Figure 1(b)), and a closed bottom (Figure 1(c)), and the like. Retaining member 14 physically retains and constrains the movement of a targeted ablation tissue before, during and after ablation

10 One or more electromagnetic energy delivery devices 18 are positioned in lumen 12'", or in retaining member 14. Electromagnetic energy delivery devices 16 can be advanced out of retainer member 14 and introduced into the selected tissue target. Alternatively, electromagnetic energy delivery devices 16 can remain stationary in lumen 12'". Cannula 12 may be advanced and retracted in order to introduce and retract electromagnetic energy delivery devices 18 in and
15 out of the soft palate tissue.

Electromagnetic energy delivery devices 18 can be of many varieties, including but not limited to an RF electrode 18 coupled to an RF energy source, a laser optical fiber 18 coupled to a laser source, a microwave antenna 18, and the like. Electromagnetic energy delivery devices 18 can have a sharpened distal
20 end in order to pierce the targeted ablation tissue. A suitable RF electrode 18 is a needle electrode.

A deployment and retraction device 20 can be used to advance and retract electromagnetic energy delivery source 18 in and out of distal end 12' and the targeted ablation tissue. Deployment and retraction device 20 includes one
25 or more actuators 20' that are mechanically coupled to electromagnetic energy delivery devices 18. Actuators 20' can be a variety of different knobs and the like that are hand activated. Actuators 20' can be positioned on an exterior surface of a handle 22 and moved axially, along gradation marks 20" to advance or retract. Gradation marks 20" provide an indication of, (i) the extension length
30 of electromagnetic energy delivery devices 18 or (ii) the length of

electromagnetic energy delivery devices 18 that is an ablation surface. Other movements of actuators 20' are suitable as long as they provide the appropriate advancement and retraction of electromagnetic energy delivery devices 18.

5 A vacuum source 21 extends to retainer member 14. Retainer member 14 provides for the retention of the uvula upon the application of vacuum. The soft palate tissue, including but not limited to the uvula, is positioned within an interior of retainer member 14. Vacuum is applied and the soft palate tissue is retained. With the soft palate tissue retained, electromagnetic energy delivery device is introduced into the soft palate tissue. Alternatively, upon application of
10 vacuum, the electromagnetic energy delivery device can include a geometry that at least partially surrounds an exterior of the soft palate tissue. Electromagnetic energy is then applied to an exterior of the soft palate.

A handle 22 includes a distal end 22' and a proximal end 22". Cannula 12 can be at least partially positioned in handle 22, or at least coupled to distal end 22'. In certain instances, cannula 12 also extends past proximal end 22". A
15 multi-plug 24 extends from proximal end 22", out of an adaptor 26 coupled to proximal end 22" or out of proximal end 12". Multi-plug 24 receives a variety of different cables or lines that are coupled to sensors 36, electromagnetic energy delivery devices 18 and other devices. For example, multi-plug 24 can receive lines coupled to, (i) sensors 36, (ii) an RF electrode 18, (iii) a laser optical fiber 18 or (iv) a microwave antenna 18. Further, a light source cable 30 can be
20 coupled to handle 22, adaptor 26 or distal end 12'.

Electromagnetic energy delivery device 18 can remain in a fixed position relative to cannula 12. In this instance, cannula 12 itself is advanced and
25 retracted from distal end 22' in order to introduce and retract electromagnetic energy delivery devices 18 in and out of the targeted ablation tissue.

An eyepiece can be coupled at a proximal end of soft tissue ablation apparatus, e.g., to proximal end 22", proximal end 12' or adaptor 26.

Figure 2 more fully illustrates distal end 12'. A visualization apparatus 32
30 is positioned in lumen 12" and can be positioned adjacent to electromagnetic

energy delivery device 18. As shown, visualization apparatus extends to distal end 12'. It will be appreciated that visualization apparatus can be slideably positioned in lumen 12''' and advance beyond distal end 12'. Further, visualization apparatus 32 can be retained in lumen 12''' and cannula 12 can itself be advanced causing visualization apparatus 32 to move. Visualization apparatus 32 includes optics, an illumination source such as a plurality of optical fibers, and the like, as is well known to those skilled in the art.

As shown in Figure 3, when electromagnetic energy delivery device 18 is advanced from distal end 12' an optical path length is established. It is within this optical path length that visualization is established. After the uvula has first received a topical anesthetic, electromagnetic energy delivery device 18 is introduced into the uvula. A suitable topical anesthetic includes but is not limited to lidocaine and can be administered out of an aperture formed in retaining member 14, cannula 12, and the like. The ablation of the targeted tissue is under full visualization. Distal end 14' holds the uvula in place as the lidocaine is sprayed and electromagnetic energy delivery device 18 introduced.

Referring now to Figure 4, an insulation layer 34 is positioned around the exterior of electromagnetic energy delivery device 18 when it is an RF electrode. A slideable insulation layer 34 surrounds electrode 12. In one embodiment insulation 34 can comprise a polyimide material, a thermal sensor 36 positioned on top of the polyimide insulation, and a .002 inch shrink wrap. The polyimide insulating layer is semi-rigid. Sensor 36 can lay down substantially the entire length of the polyimide.

Figure 5 illustrates the mechanical attachment of deployment apparatus 20 with electromagnetic energy delivery device (RF electrode 18'). Further, handle 22 is more readily adapted to be held as a trigger. An actuator 20''' is positioned at the exterior of handle 22 and is advancement back and forth along gradation marks 20'' to adjust the length of insulation layer 34 that covers RF electrode 18'. This provides a variable area of RF electrode 18' that serves as the RF electromagnetic energy ablation surface.

Referring now to Figure 6, retaining member 14 can be removed completely away from cannula 12. This permits soft tissue ablation apparatus 10 to be used in a variety of soft tissue applications besides the uvula, including but not limited to other soft palate structures, the turbinates and the like.

5 Alternatively, retaining member 14 is slightly rotated and withdrawn past distal end 12'.

Referring now to Figure 7, a flushing aperture 38 is included in retaining member 14 to spray a flushing medium across visualization apparatus 32, particularly the optics, in order to clean visualization apparatus 32. This
10 provides a clean view of the site. Additionally, a flushing aperture can be included in distal end 12'. One or more thermal sensors 36 can be positioned at distal end 14', at distal end 12', at a distal end of electromagnetic energy delivery device 18, as well as other positions to measure temperature and determine when sufficient electromagnetic energy has been applied to the soft tissue.

15 Sensors 36 provide temperature measurement and monitoring of the target to be ablated and permit a desired level of ablation to be achieved without necrosing too much tissue. This reduces damage to surrounding tissue. By monitoring the temperature at a central point within the interior of the selected mass, a determination can be made when ablation is complete. If at any time
20 sensor 36 determines that a desired ablation temperature is exceeded, then an appropriate feedback signal is received at the electromagnetic energy source which then regulates the amount of power delivered to electromagnetic energy delivery device 18.

By monitoring temperature, power delivery can be accelerated to a
25 predetermined or desired level. In the case of RF energy, impedance is used to monitor voltage and current. The readings of sensors 36 regulate voltage and current that is delivered to the tissue site. The output for these sensors 36 is used by a controller, described further in this disclosure, to control the delivery of electromagnetic energy to the tissue site. Resources, which can be hardware
30 and/or software, are connected with the thermal sensors 36, the power source

and to electromagnetic energy delivery device 18. The resources provide an output for delivering and maintaining a selected electromagnetic energy delivery device 18. Further the resources provide an output that maintains a selected RF energy for a selected length of time. If RF energy is used, the resources are
5 associated with sensors 36, a ground pad electrode (if included) as well as the RF power source for maintaining a selected power at RF electrode 18 independent of changes in voltage or current. Sensors 36 are of conventional design, including but not limited to thermistors, thermocouple, resistive wires, and the like.

10 Suitable thermal sensors 36 include a T type thermocouple with copper constantene, J type, E type, K type, thermistors, fiber optics, resistive wires, thermocouple IR detectors, and the like. It will be appreciated that sensors 36 need not be thermal sensors.

The following discussion pertains particularly to the use of an RF energy
15 source and RF electrode 18. It will be appreciated that devices similar to those associated with RF electrode 18 can be utilized with laser optical fibers, microwave devices and the like.

Referring now to Figure 8 current delivered through RF electrode 18 is measured by current sensor 42. Voltage is measured by voltage sensor 44.
20 Impedance and power are then calculated at power and impedance calculation device 46. These values can then be displayed at user interface and display 48. Signals representative of power and impedance values are received by controller 50.

A control signal is generated by controller 50 that is proportional to the
25 difference between an actual measured value, and a desired value. The control signal is used by power circuits 52 to adjust the power output in an appropriate amount in order to maintain the desired power delivered at the respective RF electrode 18.

In a similar manner, temperatures detected at the thermal sensors 36
30 provide feedback for maintaining a selected power. The actual temperatures are

measured at temperature measurement device 54, and the temperatures are displayed at user interface and display 48. A control signal is generated by controller 50 that is proportional to the difference between an actual measured temperature, and a desired temperature. The control signal is used by power
5 circuits 52 to adjust the power output in an appropriate amount in order to maintain the desired temperature delivered at the respective sensor.

Controller 50 can be a digital or analog controller, or a computer with software. When controller 50 is a computer it can include a CPU coupled through a system bus. On this system can be a keyboard, a disk drive, or other
10 non-volatile memory systems, a display, and other peripherals, as are known in the art. Also coupled to the bus are a program memory and a data memory.

User interface and display 48 includes operator controls and a display. Controller 50 can be coupled to imaging systems, including but not limited to ultrasound, CT scanners and the like.

15 Current and voltage are used to calculate impedance. Diagnostics can be performed optically, with ultrasound, CT scanning, and the like. Diagnostics are performed either before, during and after treatment.

The output of current sensor 42 and voltage sensor 44 are used by controller 50 to maintain the selected power level at RF electrode 18. The
20 amount of RF energy delivered controls the amount of power. A profile of power delivered can be incorporated in controller 50, and a pre-set amount of electromagnetic energy to be delivered can also be profiled.

Circuitry, software and feedback to controller 50 result in process control, and the maintenance of the selected power that is independent of
25 changes in voltage or current, and are used to change, (i) the selected power, including RF, microwave, laser and the like, (ii) the duty cycle (on-off and wattage), (iii) bipolar electromagnetic energy delivery and (iv) fluid delivery, including flow rate and pressure. These process variables are controlled and varied, while maintaining the desired delivery of power independent of changes

in voltage or current, based on temperatures monitored at the thermal sensors 36.

Referring now to Figure 9, current sensor 42 and voltage sensor 44 are connected to the input of an analog amplifier 56. Analog amplifier 56 can be a conventional differential amplifier circuit for use with the thermal sensors 36. The output of analog amplifier 56 is sequentially connected by an analog multiplexer 58 to the input of A/D converter 60. The output of analog amplifier 56 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D converter 60 to a microprocessor 62. Microprocessor 62 may be a model no. 68HCII available from Motorola. However, it will be appreciated that any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

Microprocessor 62 sequentially receives and stores digital representations of impedance and temperature. Each digital value received by microprocessor 62 corresponds to different temperatures and impedances.

Calculated power and impedance values can be indicated on user interface and display 48. Alternatively, or in addition to the numerical indication of power or impedance, calculated impedance and power values can be compared by microprocessor 62 with power and impedance limits. When the values exceed predetermined power or impedance values, a warning can be given on user interface and display 48, and additionally, the delivery of RF energy can be reduced, modified or interrupted. A control signal from microprocessor 62 can modify the power level supplied by power source 64.

An imaging system can be used to first define the volume of the targeted ablation tissue that will be ablated. Suitable imaging systems include but are not limited to, ultrasound, CT scanning, X-ray film, X-ray fluoroscope, magnetic resonance imaging, electromagnetic imaging and the like. The use of such devices to define a volume of a tissue mass or a tumor is well known to those skilled in the art.

Specifically with ultrasound, an ultrasound transducer transmits ultrasound energy into a region of interest in a patient's body. The ultrasound energy is reflected by different organs and different tissue types. Reflected energy is sensed by the transducer, and the resulting electrical signal is processed to provide an image of the region of interest. In this way, the volume to be ablated is ascertained.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

CLAIMS

1. An ablation apparatus, comprising:
a cannula including a distal end and a proximal end;
5 a vacuum assisted retainer device coupled to the cannula distal end, the
retainer member including a uvula receiving member configured to retain at least
a portion of the uvula with the application of vacuum;
an electromagnetic electrode coupled to an electromagnetic energy
source; and
10 a vacuum source coupled to the uvula receiving member.
2. The apparatus of claim 1, wherein the electromagnetic electrode
is at least partially positioned in an interior of the uvula receiving member.
- 15 3. The apparatus of claim 1, wherein the electromagnetic electrode
is coupled to the distal end of the cannula.
4. The apparatus of claim 1, wherein the electromagnetic electrode
is at least partially positioned in a lumen of the cannula.
20
5. The apparatus of claim 1, wherein the uvula receiving member is
has a closed bottom end and an open top end for receiving the uvula.
- 25 6. The apparatus of claim 1, wherein the electromagnetic electrode
includes a laterally deflectable distal end relative to a longitudinal axis of the
electromagnetic electrode.
- 30 7. The apparatus of claim 1, wherein an electromagnetic electrode
has a geometry configured to surround at least a portion of an exterior of the
uvula.

8. The apparatus of claim 1, wherein the electromagnetic electrode includes a thermal sensor.

5 9. The apparatus of claim 8, wherein the thermal sensor is positioned at a distal end of the electromagnetic electrode.

10 10. The apparatus of claim 1, wherein the uvula receiving member includes a thermal sensor.

11. The apparatus of claim 1, wherein the uvula receiving member includes a thermal sensor positioned on an exterior surface of the uvula receiving member.

12. The apparatus of claim 1, wherein the electromagnetic electrode is an RF electrode coupled to an RF energy source.

13. The apparatus of claim 12, further comprising:
an insulator in at least a partially surrounding relationship to the RF electrode.

20

14. The apparatus of claim 1, wherein the uvula receiving member includes a fluid distribution port.

15. The apparatus of claim 1, further comprising:
25 a visualization apparatus including a distal end extending to the uvula receiving member.

16. The apparatus of claim 15, further comprising:
an eyepiece coupled to the visualization apparatus and positioned at the proximal end of the cannula.

30

17. A method of ablating a portion of a uvula, comprising:
providing an ablation apparatus including a cannula, a vacuum assisted
retainer device coupled to the cannula distal end, the retainer member including a
uvula receiving member configured to retain at least a portion of the uvula with
the application of a vacuum, and an electromagnetic electrode;
5 introducing at least a portion of a uvula in the uvula receiving member;
applying a vacuum to the uvula and retain the uvula in the uvula receiving
member
applying electromagnetic energy from the electrode to the uvula in the
10 uvula receiving member; and
forming an ablation lesion within the uvula.
18. The method of claim 17, wherein the electrode is an RF electrode
coupled to an RF energy source.
15
19. The method of claim 18, wherein the RF ablation electrode is a
needle electrode.
20. The method of claim 18, wherein the RF ablation apparatus
20 operates in a bipolar mode.
21. The method of claim 18, wherein the RF ablation apparatus
operates in a monopolar mode.

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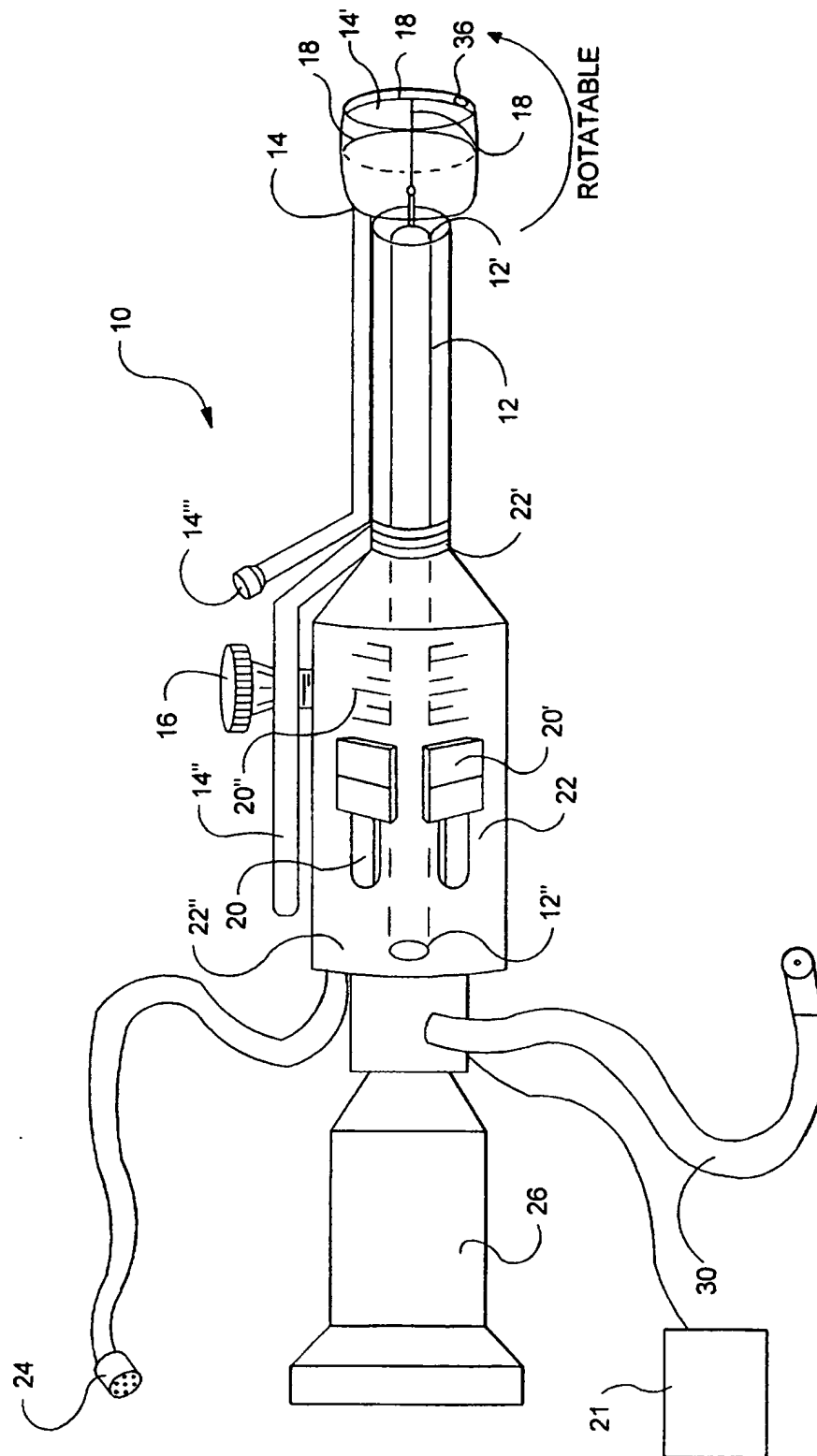


FIG. 1(A)

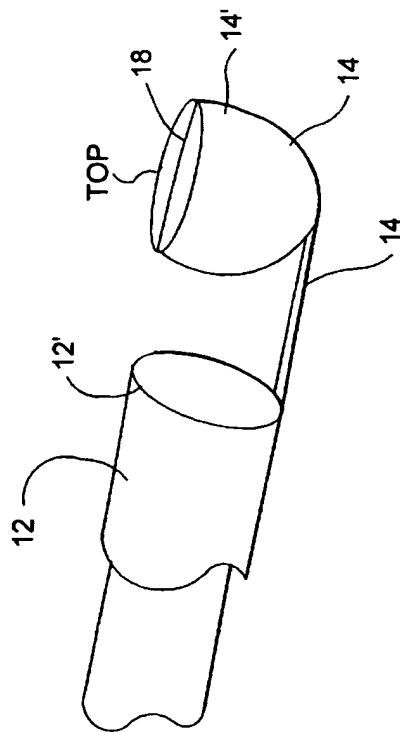


FIG. 1(b)

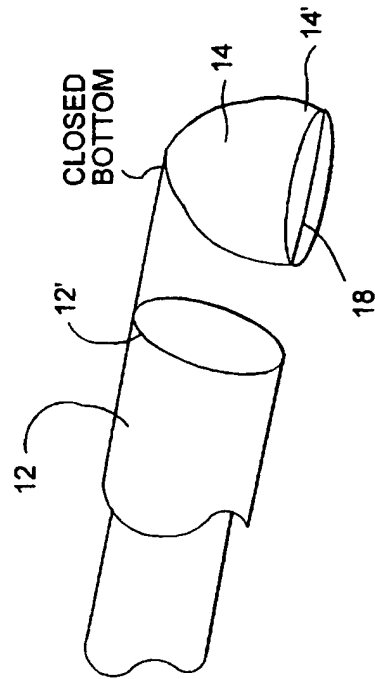


FIG. 1(c)

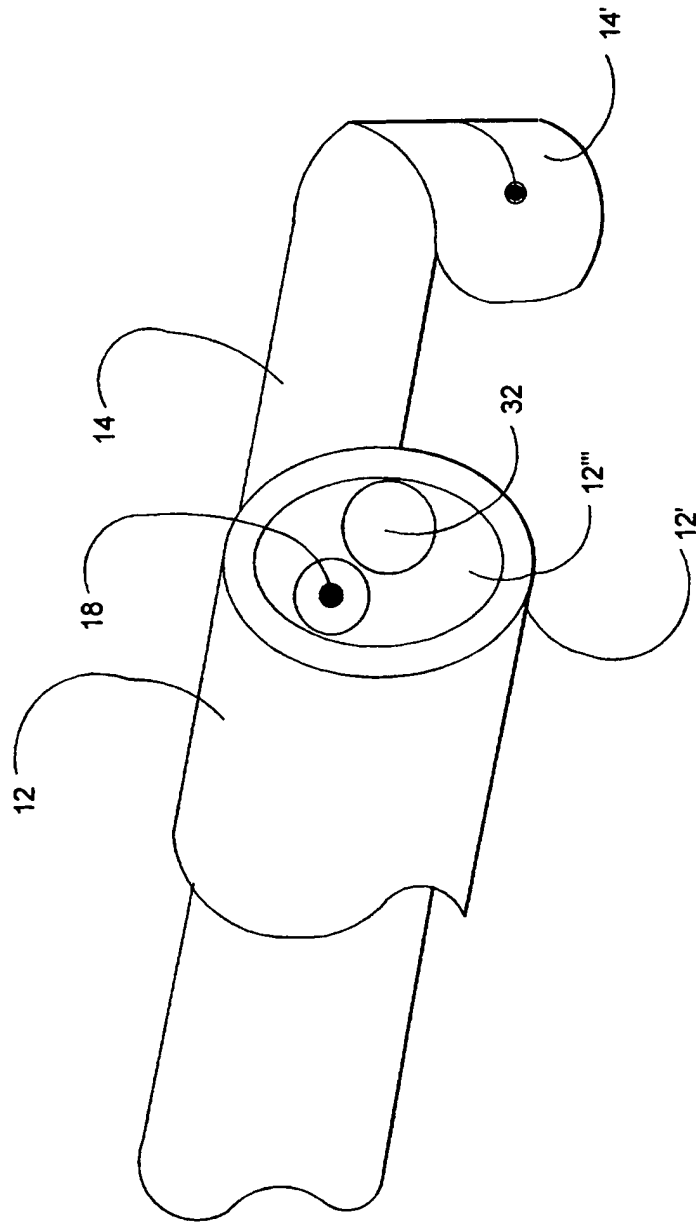


FIG. 2

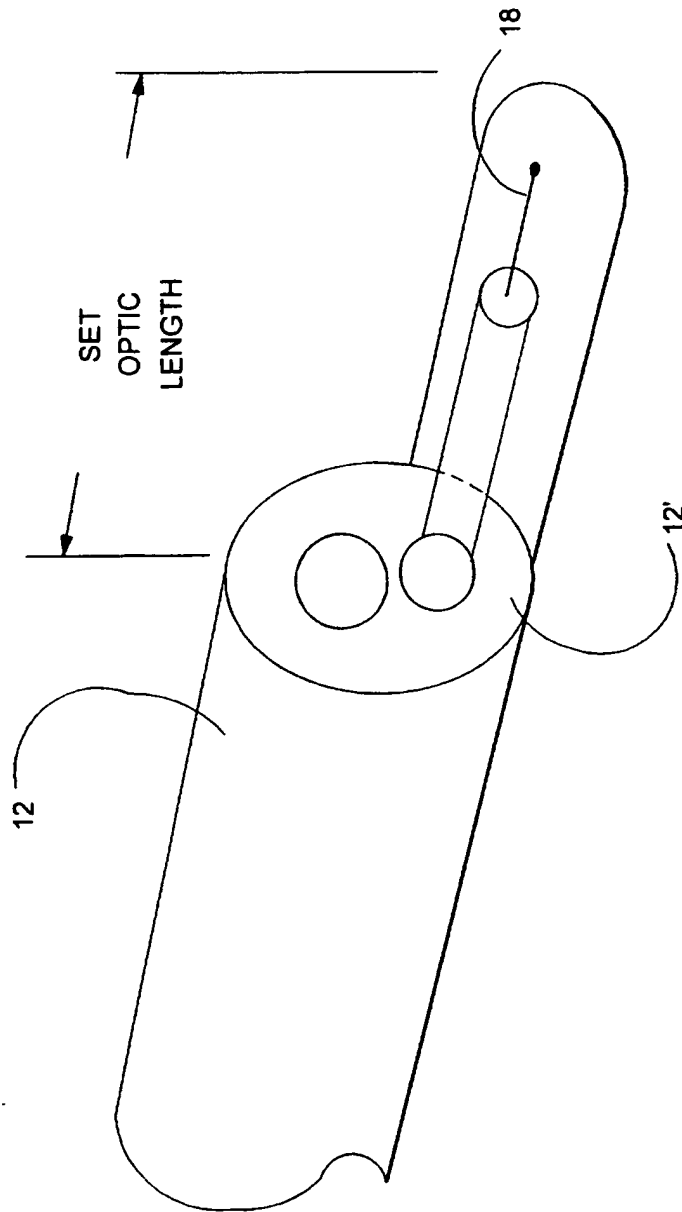


FIG.3

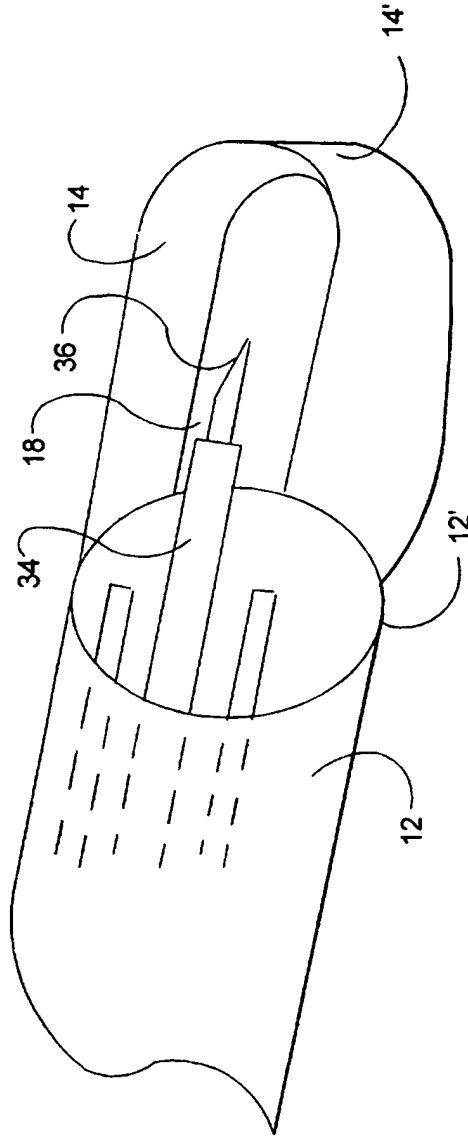


FIG. 4

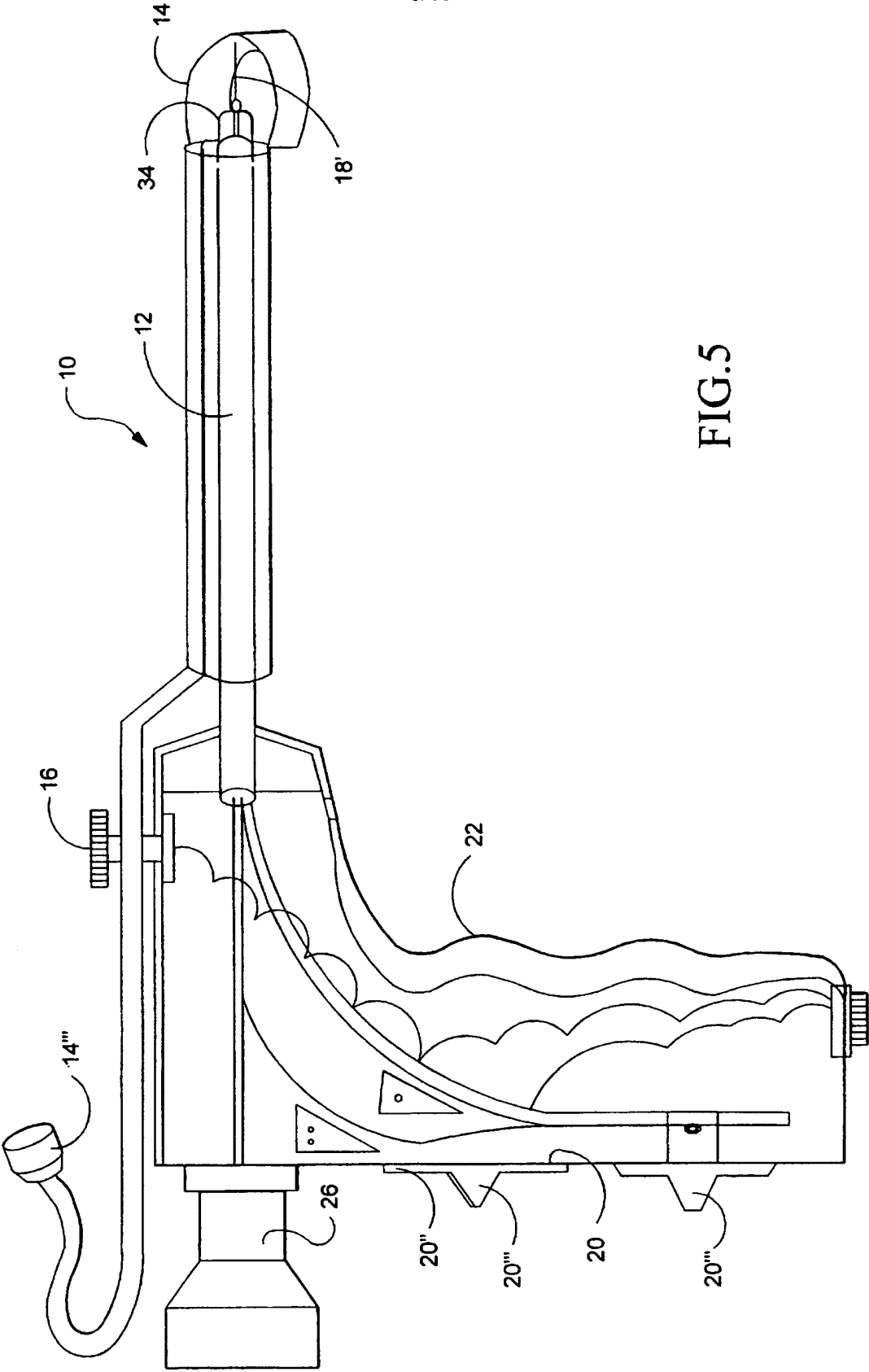


FIG. 5

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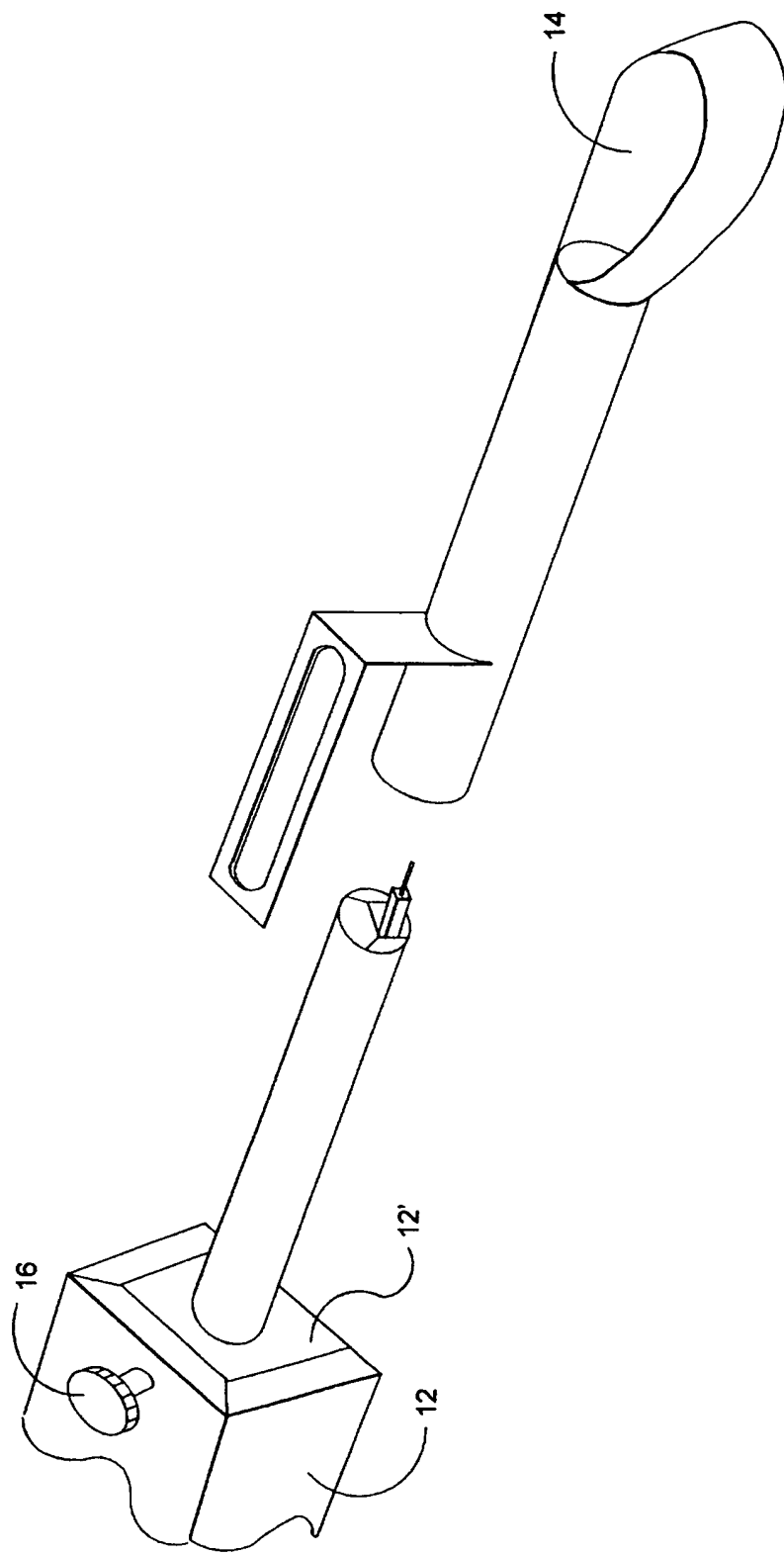


FIG. 6

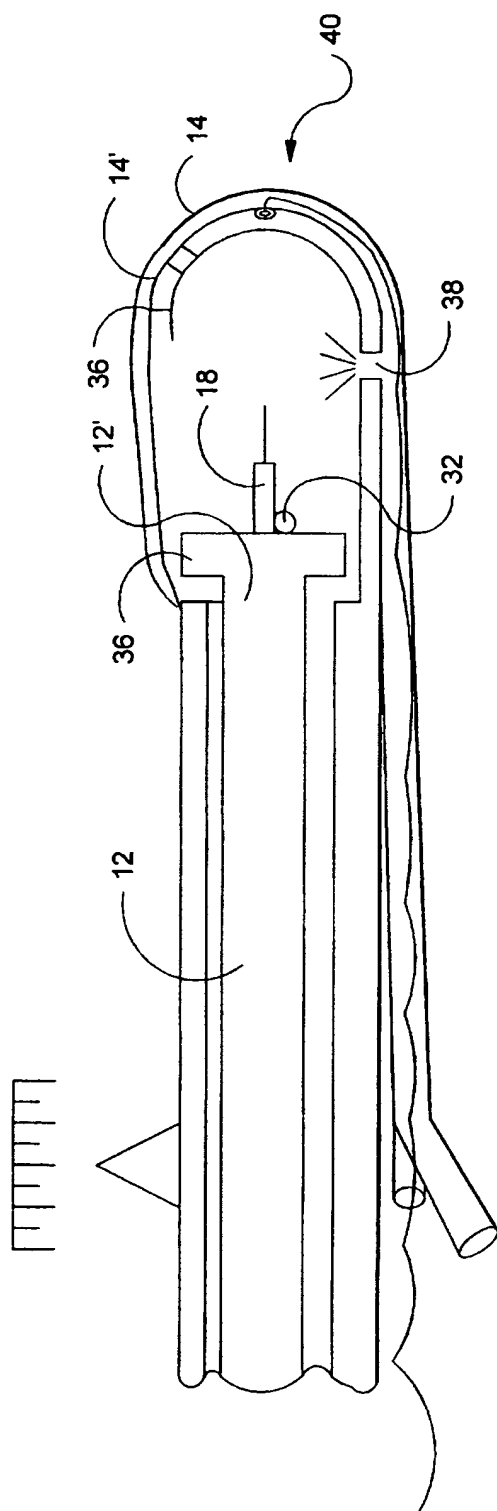


FIG. 7

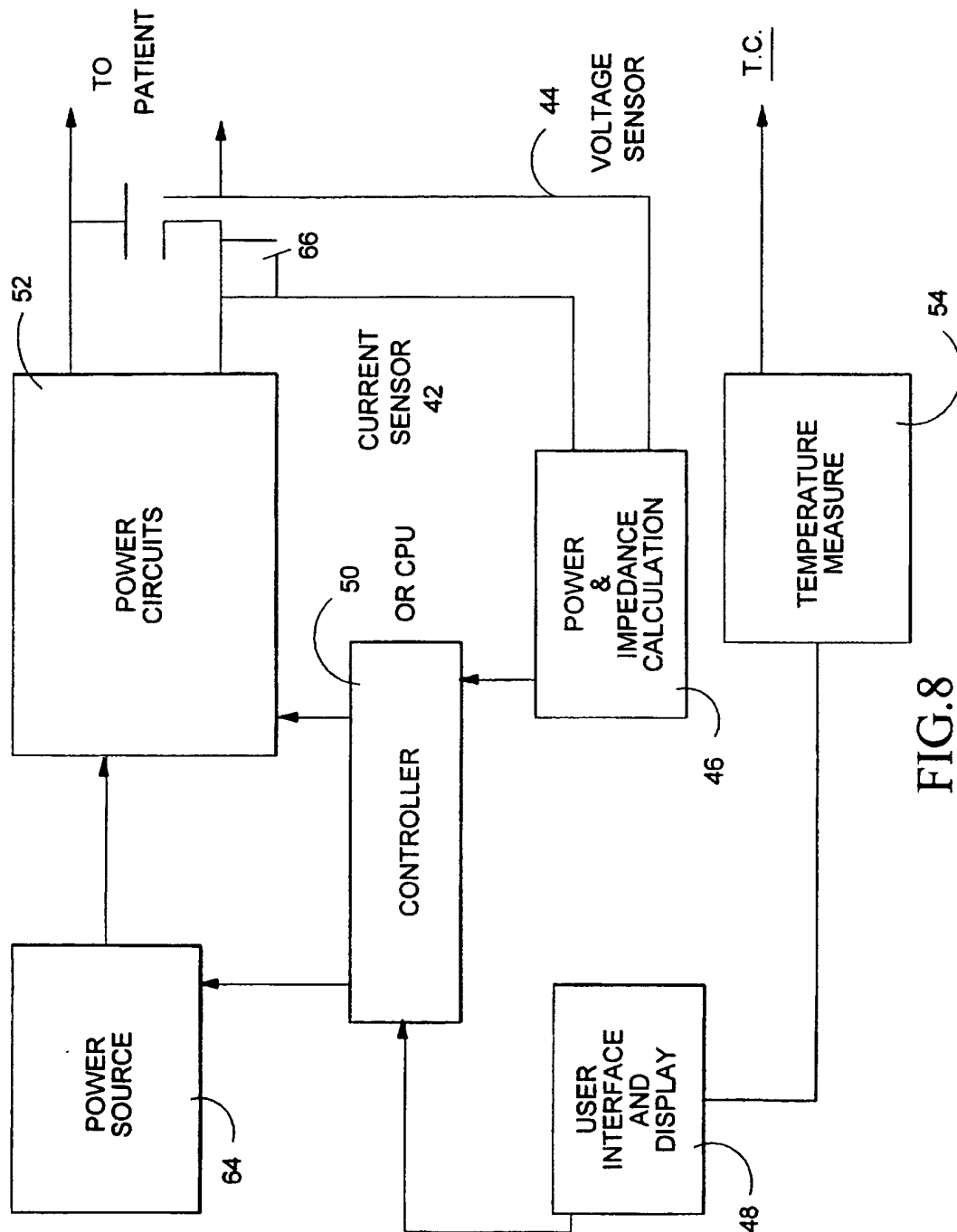


FIG.8

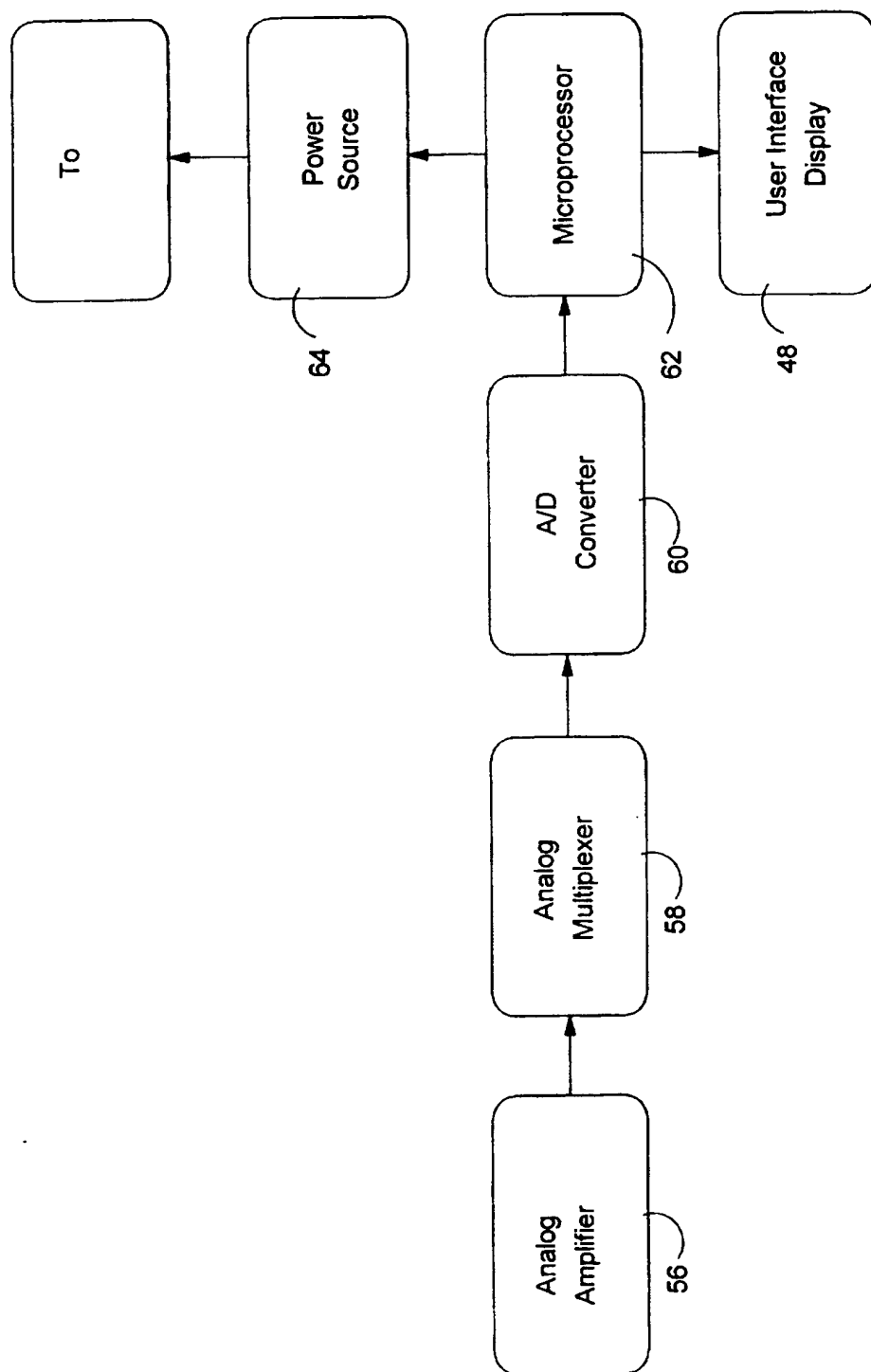


FIG.9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/03550

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2 275 167 A (BIERMAN) 3 March 1942 see page 2, left-hand column, line 34 - line 52 see page 2, right-hand column, line 72 - page 3, column 1, line 1 ---	1-16
Y	US 5 456 662 A (EDWARDS ET AL.) 10 October 1995 cited in the application see claim 1 ---	1-16
A	WO 95 05781 A (MEDTRONIC, INC) 2 March 1995 see page 7, line 15 - line 19 ---	8-10
A	WO 95 17132 A (9517132) 29 June 1995 see page 11, line 8 - line 11 see page 12, line 5 - line 22 -----	14-16

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

16 June 1997

Date of mailing of the international search report

23. 06. 97

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Fax: (+ 31-70) 340-3016

Authorized officer

Glas, J

INTERNATIONAL SEARCH REPORT

national application No.

PCT/US 97/03550

Box I (Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet))

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 17-21
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv) Method.....surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II (Observations where unity of invention is lacking (Continuation of item 2 of first sheet))

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US 97/03550

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/03550

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